SpotOn™ Temperature Monitoring System Model 370

Installation and Service Manual

Please forward to the Biomedical Engineering Department

3M™ SpotOn™

Temperature Monitoring System

Revision History

Revision	Reason for Change	Pages Affected	Date
A	New Revision - First Release	All	March 2013

Table of Contents

Section 1: Introduction **3**
About this manual 3
Intended use 3
Safety information and symbols 3
Explanation of signal word consequences 3
Proper use and maintenance 6
Read before servicing equipment 6
Description of the SpotOn temperature monitoring system 7
How it works 8

Section 2: Installation **9**
Mounting the SpotOn control unit 9

Section 3: Display Panel **11**
Display screens 11
Start-up 11
Standby 11
Ready 12
Equilibration 12
Running 12
Control unit error 12
Sensor error 12

Section 4: Troubleshooting **13**
On Mode 13
Displays 13
Errors 14

Section 5: Calibration Verification Stick **15**
Calibration verification frequency 15
Method 15

Section 6: General Maintenance **17**
Cleaning and disinfecting procedure 17
Cleaning the control unit and sensor cable 17
Disinfecting the sensor cable 17
Storage 17
Service 17

Section 7: Specifications **19**
Physical characteristics 19
Electrical characteristics 20
Temperature characteristics 20
Performance characteristics 20
Leakage current 20
Environmental conditions 20

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Section 1: Introduction

About this manual . . . 3
Intended use . . . 3
Safety information and symbols . . . 3
Explanation of signal word consequences . . . 4
Proper use and maintenance . . . 6
Read before servicing equipment . . . 6
Description of the SpotOn temperature monitoring system . . . 7
How it works . . . 8

About this manual

This Installation and Service Manual describes the setup and maintenance of the 3M™ SpotOn™ temperature monitoring system. The SpotOn temperature monitoring system is to be used by healthcare professionals in clinical environments only. Read and follow all instructions, labeling and accompanying documents supplied with the SpotOn system. Failure to follow instructions could lead to misuse of the device, device malfunction, or patient injury.

Intended use

Measure, monitor, and trend body temperature of adult and pediatric patients.

Safety information and symbols

Date of manufacture

Manufacturer

Single use only

Container quantity

CAUTION

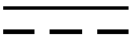
This system is subject to the European WEEE Directive 2002/96/EC.
This product contains electrical and electronic components and must not be disposed of using standard refuse collection. Please consult local directives for disposal of electrical and electronic equipment.

Defibrillation-proof type CF applied part

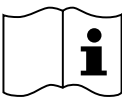
Class II equipment

Authorized Representative in the European Community

CAUTION: Recycle to avoid environmental contamination
This product contains recyclable parts. For information on recycling - please contact your nearest 3M Service Center for advice.



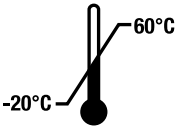
Direct current



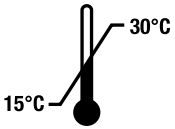
See accompanying documents

Consult operator's manual

Keep dry



Hardware temperature limits



Sensor temperature limits

Explanation of signal word consequences

WARNING: Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE: Indicates a situation which, if not avoided, could result in property damage only.

WARNINGS

1. To reduce the risks associated with access to critical patient information or equipment:
   - The SpotOn control unit is to be attached to other equipment by authorized service personnel only.
   - Do not re-install or re-locate the SpotOn control unit.
2. To reduce the risks associated with hazardous voltage, fire, and thermal energy hazards:
   - Use ONLY with 3M SpotOn system components (sensors, cables, and power supply). Do not substitute other devices for the SpotOn control unit, sensor, cables, or power supply.
   - Do not use the SpotOn temperature monitoring system (sensor, control unit, cables, or cords) in an MRI environment.
3. To reduce the risks associated with hazardous voltage and fire:
   - Keep power supply visible and accessible at all times. The plug on the power supply serves as the disconnect device. The power outlet shall be as close as practical and shall be easily accessible.
   - Use only the power supply specified for this product and certified for the country of use.
   - Use only a properly grounded power outlet; do not use extension cords or multiple portable socket outlets.
   - Do not allow the power supply to get wet.
   - Do not use the SpotOn control unit when it appears the unit or system components are damaged. Contact 3M Patient Warming technical support at 1-800-733-7775 or 952-947-1200.
   - Do not service or modify the power supply, control unit, cables, sensor, or any part of the 3M SpotOn system. There are no user serviceable parts.
4. To reduce the risks associated with fire:
   - This system is not suitable for use in the presence of a flammable anesthetic mixture with air nitrous oxide.
5. To reduce the risks associate with pressure, and crushed or entangled cords and connectors:
   - Do not allow the patient to lie on any SpotOn sensor cable or connector.
   - Always position cables and cords away from the patient's body.
   - Do not use a headband or other device to secure the SpotOn sensor to the patient.
6. To reduce the risks associated with incorrect system or sensor use:
   - Limit use of the SpotOn temperature sensor to 24 hours. Extended use may compromise skin, cause degradation of material or performance.
   - Avoid exposing the SpotOn temperature sensor, sensor cable, power supply, and control unit to surgical skin surface preparation solutions or other fluids.
   - Use an additional independent thermometer to measure body temperature during intentional hyperthermia or hypothermia therapy.
   - Confirm unanticipated temperature reading with an independent thermometer, if needed.
   - Do not reposition the SpotOn temperature sensor; repositioning may weaken the sensor adhesive, damage the sensor, or compromise the device performance.
   - Avoid placing the sensor in the center of the forehead as this may affect sensor accuracy.
7. To reduce the risks associated with exposure to biohazards:
   - Follow facilities policies and procedures for disposal of contaminated materials.
   - Always perform the decontamination procedure prior to returning the SpotOn temperature monitoring system for service and prior to disposal.
8. To reduce the risks associated with entanglement:
   - Do not leave pediatric patients unattended while using the SpotOn temperature monitoring system.

CAUTIONS

1. To reduce the risks associated with skin maceration:
   - Do not use the sensor on damaged or compromised skin.
2. To reduce the risks associated with cross-contamination:
   - Clean the sensor cable before connecting to a new sensor.
3. To reduce the risks associated with impact and facility medical device damage:
   - Do not use the SpotOn control unit as a handle to transport or to move the device to which it is attached.
   - Do not initiate temperature monitoring unless the SpotOn control unit is safely placed on a hard, flat surface or is securely mounted.
4. To reduce the risks associated with environmental contamination:
   - Follow applicable regulations when disposing of this device or any of its electronic components.

NOTICES

1. The SpotOn temperature monitoring system meets medical electronic interference requirements. If radio frequency interference with other equipment should occur, connect the unit to a different power source.
2. Federal law (USA) restricts this device to sale by or on the order of a licensed healthcare professional.
3. To avoid SpotOn temperature monitoring system damage that may impact performance:
   - Do not store the SpotOn control unit and system components in a wet or damp place.
   - Do not spray cleaning solutions onto the control unit or into the sensor cable connector.
   - Do not immerse the SpotOn temperature monitoring control unit or system components in any liquid or subject them to any sterilization process.
   - Do not use solvents such as acetone or thinner to clean the control unit; avoid abrasive cleaners.
   - Clean control unit exterior with a damp soft cloth and 70% mixture of isopropyl alcohol and water. For full cleaning procedures see “Section 5: General Maintenance” on page 21.
   - Do not immerse any of the devices or use a dripping wet cloth for cleaning.
4. The SpotOn temperature monitoring sensor is not made with natural latex material.
5. To the full extent permitted by law, the manufacturer and/or importer declines all responsibility for injury resulting from the unit being used in conjunction with unapproved system components.

Proper use and maintenance

Arizant Healthcare Inc., a 3M company assumes no responsibility for the reliability, performance, or safety of the temperature monitoring system if the following events occur:

- Modifications or repairs are performed by unqualified personnel.
- The unit is used in a manner other than that described in the Operator’s Manual.
- The unit is installed in an environment that does not meet the appropriate electrical requirements.

Read before servicing equipment

- All repair, calibration, and servicing of this equipment must be performed by 3M Patient Warming.
- There are no user serviceable parts inside the equipment or power supply.

Description of the SpotOn temperature monitoring system

The SpotOn temperature monitoring system measures the core temperature of the patient. The system is comprised of the SpotOn temperature sensor, which connects to the SpotOn control unit through the sensor cable, a power supply, and an optional monitor cable. For additional sensors, sensor cable, power supply, control unit stand, monitor cable, hook-and-loop, or foam adhesive, contact 3M Patient Warming.

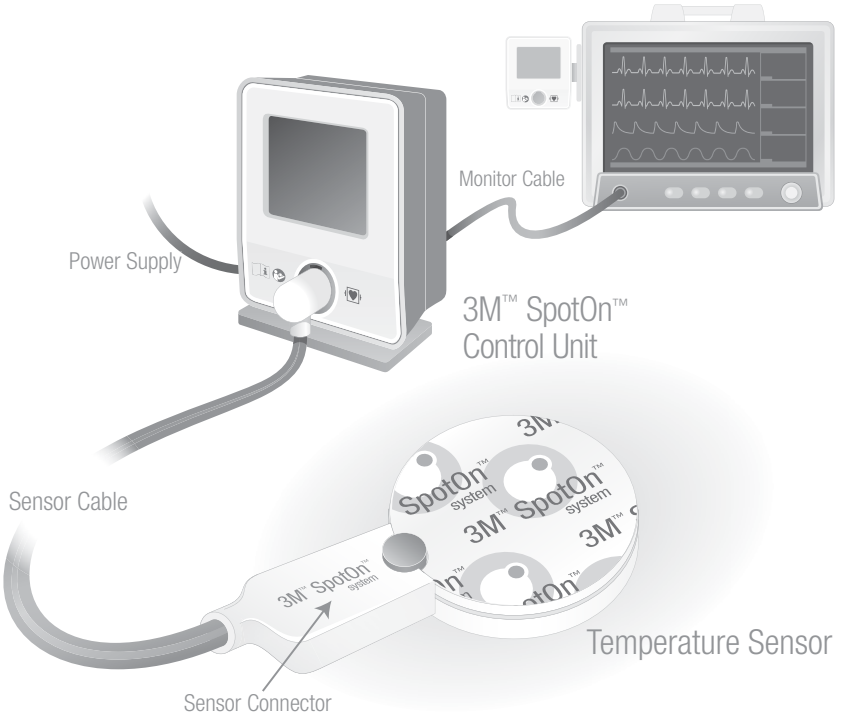


Figure 1-1: SpotOn Temperature Monitoring System

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How it works

The SpotOn temperature monitoring system uses zero-heat-flux thermometry to accurately measure a person's core temperature as characterized in Figure 1-2 below. 1) The SpotOn temperature monitoring system gently warms the sensor creating an isothermal pathway under the sensor. 2) Once equilibrated to the core temperature, skin-surface heat loss to the environment is prevented and a zero-heat-flux condition is established. 3) When the temperature sensor reaches equilibrium with the patient's core temperature, the SpotOn control unit displays an accurate, noninvasive measurement of the patient's core temperature.

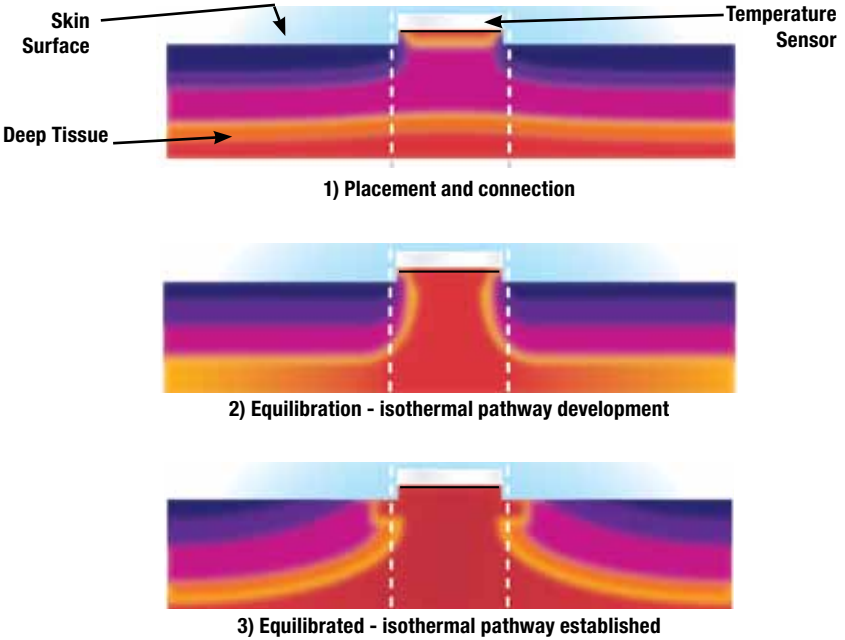

Figure 1-2: Isothermal pathway formation with zero-heat-flux technology

SpotOn control unit

The SpotOn control unit displays non-invasive core temperature measurements obtained from the SpotOn temperature sensor. The current temperature is displayed numerically, and previous temperature data is displayed graphically as a temperature trend graph. When the sensor is plugged into the sensor cable and equilibration is complete, the control unit reads up to the last two hours of stored temperature data and displays the temperature trend graph. Disconnections of the sensor from the sensor cable are indicated by gaps in the temperature trend graph. The current temperature measurement can be continuously transmitted to a patient vital signs monitor through the optional SpotOn monitor cable using a standard YSI-400 type input.

SpotOn temperature sensor

The SpotOn sensor is constructed of two layers of medical grade foam and a flexible circuit which contains a resistive warming circuit, two calibrated thermistors, and nonvolatile memory. The information that generates the temperature trend graph is stored on the SpotOn sensor. When the patient is transferred from one location to another, the SpotOn sensor is disconnected from the SpotOn sensor cable so the sensor is left in place on the patient. The SpotOn sensor may be reconnected to a different SpotOn sensor cable and control unit when the patient arrives at the next point of care. Once the SpotOn sensor is reconnected to the SpotOn sensor cable, the system will begin to reequilibrate and will regenerate the stored temperature trend graph and display the patient's current temperature. The act of disconnecting and reconnecting the SpotOn sensor from the sensor cable is indicated by a gap in the temperature trend graph.

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Section 2: Installation

WARNING:

1. To reduce the risks associated with access to critical patient information or equipment do not mount the control unit:
   - To a surface that is not flat or clean.
   - Over air vents of other equipment.
   - Over controls, displays, or buttons of other equipment.
   - Over speakers or alarms of other equipment.

Mounting the SpotOn control unit

CAUTION:

To prevent injury, mount the SpotOn temperature monitoring system at a height no higher than 84" (213 cm).

1. Use the provided hook-and-loop or foam adhesive to secure the control unit stand to any hard, flat surface (use only the 3M provided/specified control unit mounting materials).

Note:
Confirm the hook-and-loop is securely fastened together before mounting the control unit to a surface.

Recommend: Clean surface with a 70% mixture of isopropyl alcohol and water prior to applying the provided hook-and-loop or foam adhesive.

2. The SpotOn control unit's height and orientation can be adjusted by loosening/tightening the control unit stand knob on the back of the unit.

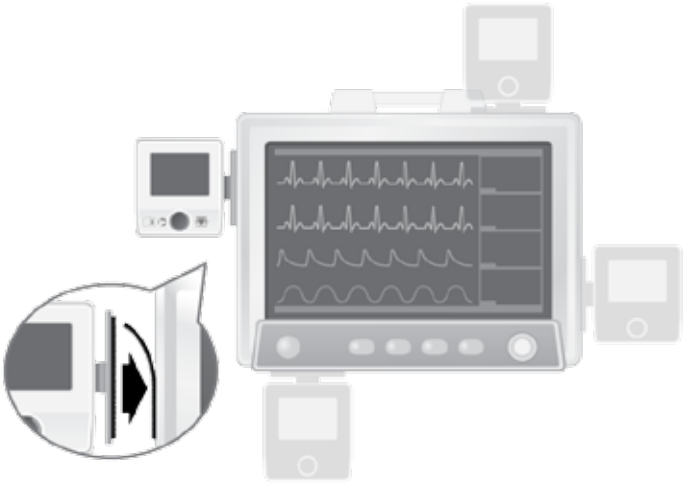


Figure 2-1: Control Unit Mounting Configuration

Section 3: Display Panel

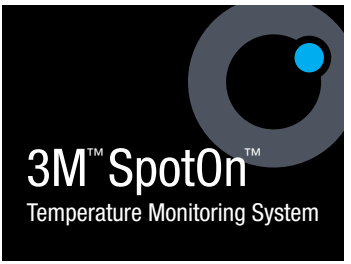
Display screens

Start-up

The start-up screen displays for approximately five seconds when the control unit is initially powered ON. The revision number of the control unit software is also displayed.

Standby

The SpotOn system graphic is displayed when the unit is not in use.



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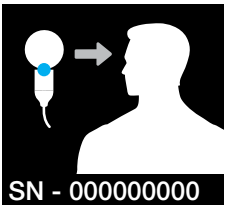
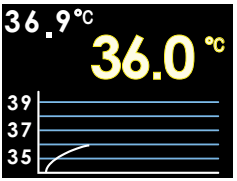
Ready

The ready screen displays the serial number of the SpotOn sensor and indicates the SpotOn sensor cable and sensor are properly attached to the SpotOn control unit. The SpotOn sensor is now ready to be attached to the patient.



Equilibration

A flashing yellow temperature display indicates the sensor has been connected to the patient and to the control unit and is in the process of equilibration. The graph below the temperature output indicates the progress of equilibration. This process will take approximately three minutes.

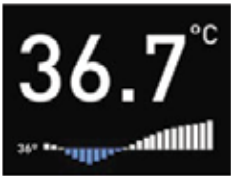


If you see a temperature in the upper left hand corner of the screen, that is the last recorded temperature that has been captured by the sensor. The sensor captures and records a temperature every five minutes.

After the equilibration is complete, the core temperature of the patient is displayed on the SpotOn control unit in bold white numbers and can be automatically transmitted to the patient monitor via the monitor cable.

Running

The running screen displays the core temperature of the patient in white. The trend graph at the bottom of the screen displays up to the last two hours of the patient's temperature in five minute increments. The bars on the graph will begin filling from the right with the 36°C always visible. The blue bars indicate that the temperature dropped below 36°C (white indicates the temperature is above 36°C).



Control unit error

The SpotOn control unit error screen displays when there is a system error. Discontinue use of unit. Contact a biomedical technician.

Sensor error

The sensor error screen displays when there is a temperature sensor or cable error. See "Section 4: Troubleshooting" on page 13 for details.

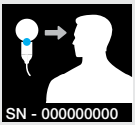
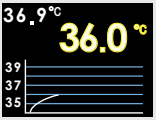
Section 4: Troubleshooting

The following conditions are listed in the order of which troubleshooting actions should be performed.

On Mode

Condition	Cause	Action
Unit does not power up.	Unit is not plugged in, or power supply is not plugged into an appropriate outlet.	Make sure the power supply is plugged into the control unit. Make sure the control unit is plugged into an appropriate power outlet.
	Unit failure.	Contact 3M Patient Warming technical service.

Displays

Condition	Cause	Action
"Ready" screen continues to display while sensor is adhered to the patient. 	Sensor not properly adhered to the patient.	Make sure the sensor is connected to the patient.
	Low patient temperature (below 29°C).	Press and hold the °C/°F button on the back of the control unit for five seconds to force the control unit into equilibration mode. The patient's temperature will then display.
	Control unit failure.	Discontinue use of unit. Contact 3M Patient Warming technical service.
"Running" screen does not appear on the control unit. 	Control unit may still be equilibrating.	Wait until the SpotOn control unit has finished equilibration. Continue use.
	Control unit failure.	Contact 3M Patient Warming technical service.
Patient temperature does not appear on the patient monitor. 	Control unit may still be equilibrating.	Wait until the SpotOn control unit has finished equilibration. Continue use.
	Monitor cable is not plugged in.	Make sure the monitor cable is plugged into the control unit and patient monitor.
	Cable failure.	• Replace monitor cable. • Contact 3M Patient Warming technical service.
	Control unit failure.	Contact 3M Patient Warming technical service after use.
The patient's temperature output on the control unit and patient monitor does not read the same value.	Cable failure.	• Confirm SpotOn monitor cable is being used. • Replace monitor cable. • Check resistance of cable. • Contact 3M Patient Warming technical service.

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Errors

Error Screen	Condition	Cause	Action
	E-1 through E-99	Sensor not properly connected to the sensor cable.	Make sure the sensor is connected to the sensor cable, by disconnecting and reconnecting the sensor.
		Sensor failure.	Replace sensor.
		Cable failure.	• Replace sensor cable. • Contact 3M Patient Warming technical service.
	E-100 and up	Control unit failure.	• Disconnect the unit from power source. • Allow 30-60 seconds for the unit to reset. • Reconnect the unit to the power source to determine if the unit reset or if it is a permanent error.
			Discontinue use of the unit. Contact a biomedical technician.

Section 5: Calibration Verification Stick

Calibration verification frequency

Every 12 months or according to institutional protocol.

Tools and equipment

- Calibrated digital multi-meter
- Model 90111 Calibration verification stick

Method

1. Connect the power supply to the back of the SpotOn control unit (see Figure 5-1: Back of Control Unit).
   Plug the power supply into an appropriate outlet. The standby screen will illuminate.
2. Connect the SpotOn sensor cable to the front of the control unit (see Figure 5-2: Front of Control Unit).

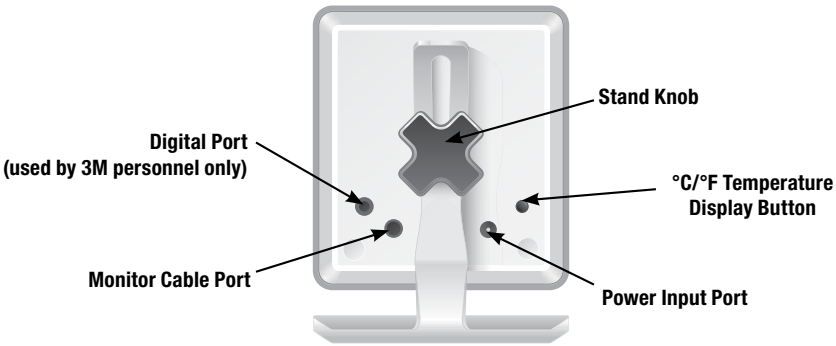

Figure 5-1: Back of Control Unit

Figure 5-2: Front of Control Unit

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3. Connect the SpotOn calibration verification stick to the sensor cable. Ensure the verification stick is fully inserted into the sensor cable.

4. The screen shows the actual calibrated thermistor readings for the skin and heater thermistors. The calibration verification stick contains a precision resistor for each calibrated thermistor with a known reference value corresponding to a reference temperature. Verify that the reference temperature for each calibrated thermistor matches the displayed value (36.0 ± 0.1°C, 96 .8± 0.2°F)

5. If the reference temperatures are within acceptable limits, continue with steps below.
If the reference temperatures are outside of the acceptable limits, discontinue use of the SpotOn temperature monitoring system. Contact 3M patient warming technical service at 1-800-733-7775.

Figure 5-3: Calibration screens (Celsius and Fahrenheit)

6. Plug the monitor cable to the monitor port on the back of the control unit.
7. Wait for the control unit to calibrate and start emulating data. The internal relay will "click" and the display will refresh when the emulation is active.
8. Set the multi-meter to the 2000 ohm range.
Note: Zero the multi-meter as necessary for all resistance measurements.
9. Hold the digital multi-meter leads to the tip and the ring on the end of the monitor cable.
10. Confirm the reading on the multi-meter is 1412 ohms $^{+}$/–15 ohms.
11. If the reading on the multi-meter is within acceptable limits, return the SpotOn temperature monitoring system to use.
If the reference reading on the multi-meter is outside of the acceptable limits, discontinue use of the SpotOn temperature monitoring system. Contact 3M patient warming technical service at 1-800-733-7775.

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Section 6: General Maintenance

Cleaning and disinfecting procedure

CAUTION:

- Do not immerse any of the devices or use a dripping wet cloth for cleaning. Moisture may seep inside the device and damage the electrical components and lead to incorrect temperature reporting.
- Do not spray cleaning solutions onto the control unit or into the sensor cable connector. Damage to the control unit or sensor cable connector may occur.

Cleaning the control unit and sensor cable

Clean the SpotOn control unit on an as-needed basis or per facility policies and procedures for cleaning electronic equipment. Clean the sensor cable between each use.

1. Disconnect power supply from power outlet.
2. Use a slightly damp soft cloth moistened with a mild, nonabrasive cleaning solution to clean the device surfaces, cords, and cables. Avoid getting liquid into electronic ports.
3. Dry with a separate soft cloth.

Disinfecting the sensor cable

1. Clean the devices as described above.
2. Wipe down the control unit and cable using a damp soft cloth and 70% isopropyl alcohol solution. Avoid getting liquid into electronic ports.
3. Dry with a separate soft cloth.

Storage

Notice: Do not store the SpotOn control unit and system components in a wet or damp place. Damage to the electrical components may occur.

Store all SpotOn components at room temperature and in a dry place when not in use.

Service

All service must be performed by 3M Patient Warming or an authorized service technician. Call 3M Patient Warming Customer Service at 1-800-733-7775 for service information..

Section 7: Specifications

Physical characteristics

Dimensions of Control Unit
9.3 cm (3.7 in) high, extendable to 11.4 cm (4.5 in) high

7.1 cm (2.8 in) wide, 4.3 cm (1.7 in) deep

Weight of Control Unit
128 g (4.5 oz)

Dimensions of Sensor
4.1 cm (1.6 in) diameter, 0.5 cm (0.2 in) thick

Length of the Sensor Cable
400 cm (158 in)

Classification
MEDICAL - GENERAL MEDICAL EQUIPMENT AS TO ELECTRICAL SHOCK, FIRE AND MECHANICAL HAZARDS ONLY IN ACCORDANCE WITH UL 60601-1; CAN/CSA-C22.2, No. 60601-1; ANSI/AAMI ES60601-1:2005 CSA-C22.2 No. 601-1:08; Control No. 4HZ8. No.4HZ8

Classified under IEC 60601-1 Guidelines (and other national versions of the Guidelines) as Class II, Type CF, Defibrillation-Proof, Ordinary Equipment. Conforms to EN12470. Not suitable for use in the presence of flammable anesthetic mixtures with air or nitrous oxide.

Classified by Underwriters Laboratories Inc. with respect to electric shock, fire, and mechanical hazards only, in accordance with UL 60601-1, IEC 60601-1, and Canadian/CSA C22.2 No. 601.1. ANSI/AAMI ES 60601-1; 2005.Classified under the Medical Device Directive as a Class IIb device.

Accuracy
25°C to 43°C ± 0.2°C

Sensor Material
Medical grade foam and adhesive

PET flexible circuit

Recommended Calibration Check
Every 12 months or according to institutional protocol.

Sensor Shelf Life
36 months

Digital Port (used by 3M personnel only)
Serial output 0 [-12 to + 12]

Monitor Cable Port
Provides a resistance that corresponds to a YSI-400 thermistor at the displayed temperature. It is electrically isolated from the SpotOn control unit.

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Electrical characteristics

External power supply
100-240 VAC, 50-60 Hz
Output; 5 VDC
Class II, double insulated medical grade

Maximum heating power
2 W

Temperature characteristics

Over-temperature cutoff
43°C - Skin thermistor reading

44.5°C - Heater thermistor reading

Performance characteristics

Equilibration time
Approximately three minutes

Time response
Approximately three minutes

Measurement locations
Patient's lateral forehead above the orbital ridge

Measurement range
25°C - 43°C

Measurement readout
Celsius or Fahrenheit

Leakage current
CF classification. Meets leakage current requirements in accordance with UL 60601-1 and IEC 60601-1.

Environmental conditions

Ambient temperature range
10°C to 40°C (50°F to 104°F)

Storage and transport temperature range
-20°C to 60°C (-4°F to 140°F)

Store all components at room temperature and in a dry place when not in use.

Operating humidity
10 to 75% RH, noncondensing

Atmospheric pressure range
80 kPa to 106 kPa (12 PSI to 15 PSI)

Oxygen environment
The sensor only is suitable for use in the presence of an oxygen enriched environment.

Calibration Verification Log

Date	Action Performed
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____
	Calibration check reference temperatures _____ Cable monitor resistance _____

CE 0086

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